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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/865,637	05/25/2001	Bernard Rentier	B45082D1	4711

7590 03/11/2003

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EXAMINER

MOSHER, MARY 10

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/865,637

Applicant(s)

Rentier et al

Examiner

Mosher

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/26/02
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-21 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). 10
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Interview Summary

Application No.
09/865,637

Applicant(s)
Rentier et al

Examiner
Mosher

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All participants (applicant, applicant's representative, PTO personnel):

(1) Mosher (3) _____
(2) William Majarian (4) _____

Date of Interview 3/6/03

Type: a) ☒ Telephonic b) ☐ Video Conference
c) ☐ Personal [copy is given to 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☒ Yes e) ☐ No. If yes, brief description:

Fax of amendment proposed by MM

Claim(s) discussed: 13, 14, 16, and 20

Identification of prior art discussed:
none

Agreement with respect to the claims f) ☐ was reached. g) ☒ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments:

MM proposed examiner's amendment. WM indicated client consultation would take time, suggested action instead.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

i) ☒ It is not necessary for applicant to provide a separate record of the substance of the interview (if box is checked).

Unless the paragraph above has been checked, THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Examiner's signature, if required

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DETAILED ACTION

Claim Rejections - 35 USC § 112

Claims 13-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 13 and 14, as amended, now recite ...”IE63 protein or a fragment or derivative thereof...”. However, the claims do not place any limits on the fragments or the derivatives. Is dipeptide intended as a “fragment?” Since any sequence can be derived from another sequence by successive substitutions, insertions, and deletions, how would one distinguish an IE63 “derivative” from any other protein or nucleic acid sequence? Because the metes and bounds of “fragment or derivative” are undefined, the claims are seen as indefinite.

Claims 13-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method using a pharmaceutical composition, comprising isolated VZV IE63 protein or nucleic acid, where the composition induces a humoral or cellular immune response, does not reasonably provide enablement for a composition comprising any fragment or derivative of IE63 or an immunoprotective response. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. First, in regard to “fragment or derivative,” the specification provides no guidance as to what parts of the IE63 sequence can be changed or removed while retaining desirable properties. Considering the broad scope of “fragment or derivative”, the infinite number of possible changes to the sequence, and the lack of

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guidance, it is concluded that undue experimentation would be required to make and use the full scope of “fragments or derivatives” encompassed by the claims. In addition, regarding claim 16, the specification teaches anchorless derivatives of glycoproteins, but does not provide any guidance as to other derivatives.

Second, in regard to “immunoprotective response”, the specification provides evidence of humoral and cellular immune responses against IE63, and one skilled in the art would readily accept that inducing such immune responses would be useful, regardless of whether or not the immune response completely protects against VZV-induced disease. However, the specification does not provide evidence that the immune response is sufficient to protect against VZV disease. Since protection against herpesvirus diseases has been difficult to achieve in the past, one skilled in the art would have reason to doubt an unsupported assertion of an immunoprotective response. Therefore, enablement is seen as limited to the useful humoral and cellular immune responses, absent undue experimentation.

The following changes to the claims would place the application in condition for allowance:

13. A method of treating a patient suffering from or susceptible to Varicella Zoster virus infection, comprising administering to a patient a pharmaceutical composition comprising an isolated Varicella Zoster Virus IE63 protein [or a fragment or derivative thereof] and a pharmaceutically acceptable excipient, wherein the composition induces [an immunoprotective] a humoral or cellular immune response without significant, adverse side effects.

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14. A method of treating a patient suffering from or susceptible to Varicella Zoster virus infection, comprising administering to a patient a pharmaceutical composition comprising an isolated nucleic acid encoding IE63 [or a fragment or derivative thereof], wherein the composition induces [an immunoprotective] a humoral or cellular immune response without significant, adverse side effects.

16. A method of treating a patient suffering from or susceptible to Varicella Zoster virus infection as claimed in claim 15, wherein the other VZV antigens are selected from the group, gpI, gpII, gpIII, gpIV, gpV or IE62 or [immunological functional derivative] anchorless derivatives thereof.

20. A method of producing a pharmaceutical composition comprising an isolated Varicella Zoster virus IE63 protein [or fragment or derivative thereof], or an isolated nucleic acid encoding a Varicella Zoster virus IE63 protein [or fragment or derivative thereof], comprising mixing said protein or [fragment or derivative thereof] or said nucleic acid with a pharmaceutically acceptable excipient.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is (703) 308-2926. The examiner can normally be reached on Monday -Thursday and alternate Fridays from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is now (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

March 10, 2003


MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1648
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